588 DOSTARLIMAB + CHEMOTHERAPY FOR THE TREATMENT OF PRIMARY ADVANCED OR RECURRENT ENDOMETRIAL CANCER (PA/REC) IN THE RUBY TRIAL: POST HOC ANALYSIS OF THE COSTS OF GRADE ≥3 ADVERSE EVENTS (AES)

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Background In the RUBY trial (NCT03981796), dostarlimab + carboplatin-paclitaxel (CP) significantly increased progression-free survival (PFS) compared with placebo+CP in patients with pA/rEC. Grade ≥3 AEs were more frequent with dostarlimab+CP vs placebo+CP. This analysis estimated the difference in per-patient costs of grade ≥3 AEs with dostarlimab +CP vs placebo+CP.

Methods This AE cost model used grade ≥3 treatment-emergent AE (TEAE) and treatment-related AE (TRAE) data from RUBY part 1. Grade ≥3 AEs are likely to require specialized clinical treatment and/or hospitalization; as a surrogate, management costs were extracted from the US Healthcare Cost and Utilization Project using 2020 inpatient hospitalization data. In the base-case analysis, mean per-patient costs for each AE were calculated by multiplying management cost by the number of AEs observed and dividing by the number of participants. In a scenario analysis, number needed to treat to harm (NNTH) or benefit (NNTB) was derived from the risk difference for each AE, and mean per-patient cost differences were calculated by dividing management cost by NNTH or NNTB. All analyses were performed in the mismatch repair-deficient (dMMR)/microsatellite instability-high (MSI-H) and intention-to-treat (ITT) populations.

Results In the base-case analysis in the dMMR/MSI-H group, aggregate per-patient costs were $26,968 (US$) with dostarlimab+CP vs $35,862 with placebo+CP (difference: −$8,894) for TEAEs (**figure 1**) and $19,775 vs $26,005, respectively, (difference: −$6,230) for TRAEs (**figure 2**). Lower predicted AE costs for dostarlimab+CP vs placebo+CP were driven by higher costs of managing decreases in neutrophil and white cell counts, which occurred more frequently in the placebo arm. In the ITT population, aggregate per-patient costs were $28,199 with dostarlimab+CP vs $25,219 with placebo+CP (difference: $2,980) for TEAEs and $19,375 vs $19,156, respectively, (difference: $219) for TRAEs. The higher predicted costs for dostarlimab+CP in the ITT population were driven by comparatively smaller differences in costs of neutrophil and white cell count decreases but higher costs of anemia, sepsis, peripheral neuropathy, and metabolic enzyme derangements. AE cost differences were qualitatively similar in the scenario analysis.

Conclusions In the dMMR/MSI-H population, grade ≥3 TEAE and TRAE costs were predicted to be substantially lower for dostarlimab+CP. In the ITT population, grade ≥3 TEAE costs were predicted to be somewhat higher for dostarlimab+CP, while grade ≥3 TRAE costs were similar between arms. Together with the significant PFS benefits, these results further support the use of dostarlimab+CP as a new standard of care, especially in patients with dMMR/MSI-H pA/rEC.

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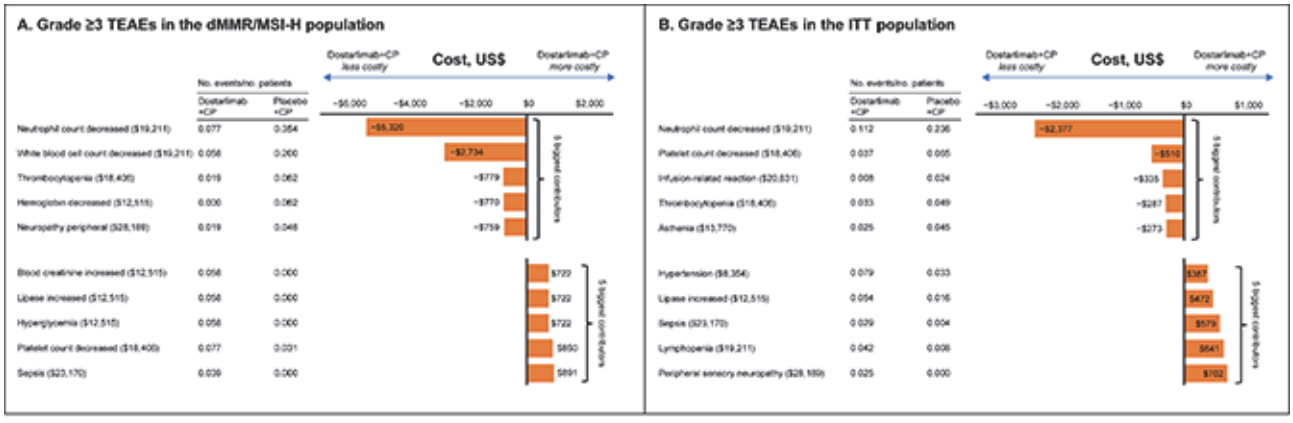
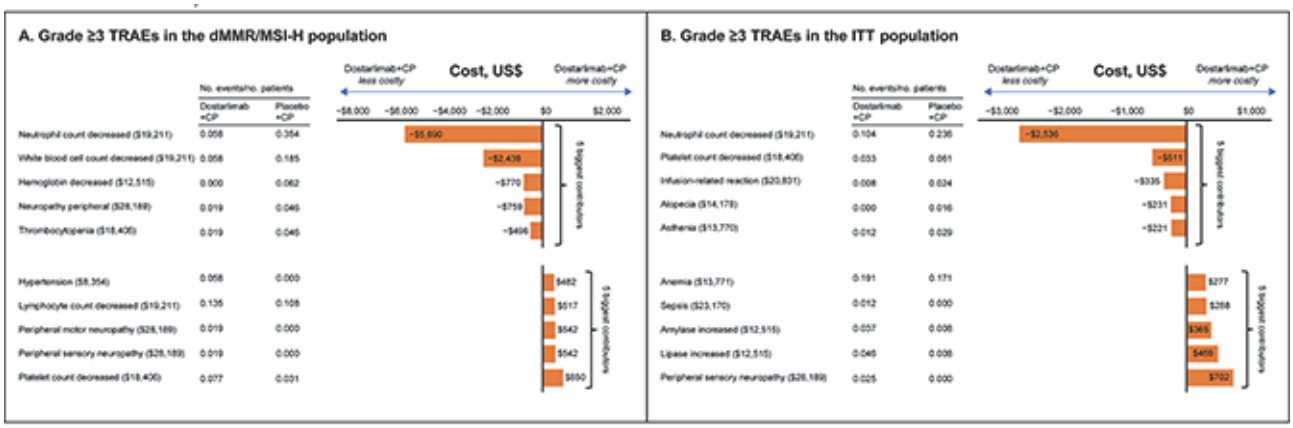
Trial Registration U.S. National Library of Medicine ClinicalTrials.gov, NCT03981796



Abstract 588 Figure 1 Grade 23 TEAEs in the (A) dMMR/MSI-H and (B) ITT populations. In each panel, the 5 biggest positive (higher costs for placebo+CP) and negative (higher costs for dostarlimab+CP) contributors are shown.



CP, carboplatin-paclitaxel; dMMR/MSI-H, mismatch repair deficient/microsatellite instability high; ITT, intention to treat; TRAE, treatment-related adverse event.

Abstract 588 Figure 2 Grade 23 TRAEs in the (A) dMMR/MSI-H and (B) ITT populations. In each panel, the 5 biggest positive (higher costs for placebo+CP) and negative (higher costs for dostarlimab+CP) contributors are shown.

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